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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,674	02/22/2002	Boris P. Kovatchev	00438-02	3616

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
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EXAMINER

ASTORINO, MICHAEL C

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,674

Applicant(s)

KOVATCHEV ET AL.

Examiner

Michael C Astorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-8 and 10-18 is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges the amendment filed June 28, 2004, wherein claims 1-4, 6-8, and 10-20 are pending in the application, and claims 5 and 9 have been cancelled. Additionally claims 1, 6, 10, 14, 19 and 20 have been amended.

The indicated allowability of claims 19-20 is withdrawn in view of the newly discovered reference(s) to Kovatchev, B.P., Cox, D.J., Gonder-Frederick, L.A. and Clarke, W. (1997). "*Symmetrization of the Blood Glucose Measurement Scale and Its Applications.*" Diabetes Care, Vol. 20, No. 11, pp655-1658. (Cited by applicant) Rejections based on the newly cited reference(s) follow.

Information Disclosure Statement

The information disclosure statement filed June 28, 2004, complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, the examiner's initials have been provided for each citation, the document has been signed and dated, and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovatchev et al., "*Symmetrization of the Blood Glucose Measurement Scale and Its Applications. Diabetes Care*".

Claim 19. (currently amended) A method for assessing the risk of hypoglycemia based on a Low BG Index comprising the steps of:

- receiving and recording a BG history profile (see page 1656);
- transforming the BG history profile to obtain a symmetrical distribution scale (figure 2);
- introducing a BG Risk Function to obtain a Low BG Index (see Procedure section); and
- assessing the risk of hypoglycemia based on the Low BG Index (figure 2).

Claim 20. (currently amended) An apparatus for assessing the risk of hypoglycemia based on a Low BG Index comprising;

- an interface for receiving a BG history profile (see Procedure section);
- a BG history profile transformation module for transforming the BG history profile into a symmetrical distribution scale (Figure 2);
- a BG Risk Function module for obtaining a Low BG Index (see Procedure section); and
- a hypoglycemia risk classification module for determining the assessed risk of hypoglycemia based on the Low BG Index (Figure 2).

3. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 28, 2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C Astorino whose telephone number is 703-306-9067. The examiner can normally be reached on Monday-Friday, 10:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ERIC F WINAKUR
PRIMARY EXAMINER